

Histrelin Acetate

Product:

HISTRELIN ACETATE (Vantas®) 50mg subdermal implant

Class of drugs:

Luteinizing hormone-releasing hormone agonist

Indication:

Treatment of advanced prostate cancer

Manufacturer:

Paladin Labs Inc.

CED Recommendation

The CED recommended that histrelin (Vantas) not be funded through Ontario Public Drug Programs, on the basis that the supporting clinical evidence for this drug is poor.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to fund histrelin (Vantas) through Ontario Public Drug Programs.

Status

No funding through Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Histrelin is indicated for the treatment of advanced (metastatic) prostate cancer. It belongs to a class of drugs known as luteinizing hormone-releasing hormone (LHRH) agonists. Currently funded LHRH agonists include buserelin, goserelin, leuprolide, and treptorelin.
- ◆ The Committee reviewed two small, low-quality, clinical studies evaluating the use of histrelin in the treatment of advanced prostate cancer. The two studies suggest that histrelin is similar in efficacy and safety as other LHRH agonists.
- ◆ Large, good-quality studies are not available to support the use of this drug.
- ◆ There is no evidence that histrelin is clinically better than other LHRH agonists.
- ◆ Histrelin costs \$4,074 per year. This is comparable to some of the lower cost LHRH agonists currently listed on the Formulary.
- ◆ Overall, the Committee indicated that evidence supporting the use of histrelin is of poor quality. Furthermore, this drug does not provide any therapeutic or economic advantages over existing Formulary alternatives. For these reasons, the Committee recommended that histrelin not be funded.

Background:

Prostate cancer is the uncontrolled (malignant) growth of cells in the prostate gland. Advanced or metastatic prostate cancer is cancer that has spread from the prostate gland to nearby lymph nodes, bones, or other organs.

Treatment options for advanced prostate cancer include hormonal therapy, surgery, chemotherapy and radiotherapy. Luteinizing Hormone-Releasing Hormone (LHRH) agonists are a form of hormonal therapy. Prostate cancer cells are dependent on testosterone for growth. LHRH agonists work by suppressing the production of testosterone; this process is known as chemical castration.

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Detailed Discussion:

- ◆ The Committee considered two small, poor-quality (open label, < 200 subjects and one unpublished) clinical studies evaluating the use of histrelin in the treatment of advanced prostate cancer.
- ◆ The small, unpublished study compared histrelin to goserelin (Study 302). The study found no significant differences between patients on histrelin and those on goserelin in efficacy measures such as time to reach chemical castration, number of patients who achieved castrate testosterone levels, disease progression, and prostate-specific antigen response. The study also reported no significant difference in the rate of adverse events between histrelin and goserelin.
- ◆ In the second study (Schlegel et al. J Urol 2006;175:1353), all patients were given histrelin treatment. The study had no control group to actually compare the benefit of histrelin versus other therapies. Study results suggest that histrelin is similar in efficacy and adverse effects as other LHRH agonists.
- ◆ There are no large, good-quality clinical trials assessing the efficacy and safety of histrelin.
- ◆ There is also no evidence that histrelin is therapeutically superior to other LHRH agonists.
- ◆ Common side effects of histrelin include hot flashes, impotence and reduced libido.
- ◆ The annual cost of histrelin is \$4,074, which is comparable to some of the lower cost LHRH agonists currently listed on the Formulary.
- ◆ Histrelin is administered once yearly as an implant under the skin. Removal of this implant can be difficult or painful, requiring some specific expertise. Expulsion of the implant from the skin is also possible. Moreover, as a year-long implant, the cost of treatment is paid all at once. This can lead to wastage and increased costs if therapy is discontinued prior to the end of the year.

- ◆ **Overall, the Committee indicated that evidence for the use of histrelin is of poor quality. Furthermore, this drug does not provide any therapeutic or economic advantages over already funded alternatives. For these reasons, the Committee recommended that histrelin not be funded.**
- ◆ The CED worked jointly with a subcommittee involving cancer experts to review this cancer drug, as is done for all other cancer drug treatments.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) recommended that histrelin acetate (Vantas®) not be listed.



Ministry of
Health and Long-Term Care
Ontario Public Drug Programs

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